FEB 20 2009

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k080481

Applicant:	Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318
Contact person:	Rachelle Parsons Senior Regulatory Affairs Specialist, RAC Phone: 952.368.1227 Fax: 952.368.7610
Date prepared:	August 20, 2008
Proprietary name:	Access® Myoglobin and Access Myoglobin Calibrators on the Access Immunoassay Systems
Common name:	Myoglobin Enzyme Immunoassay
Product classification:	Class II
Product code:	DDR; JIS
Predicate device:	Access Myoglobin Assay – k021229
Device description:	The Access Myoglobin reagent and calibrators, the Access Immunoassay Analyzers comprise the Access Immunoassay Systems for the quantitative determination of cardiac Myoglobin in human serum and plasma.
Intended use:	The Access Myoglobin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of myoglobin levels in human serum and plasma using the Access Immunoassay Systems.

Comparison of Technological Characteristics

Attribute	Access Myoglobin	Access Myoglobin (With Modification to IFU)
Intended Use	For the quantitative determination of myoglobin levels in human serum and plasma.	For the quantitative determination of myoglobin levels in human serum and plasma.
Assay principles	A two site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with mouse monoclonal anti-myoglobin-alkaline phosphatase conjugate, mouse monoclonal anti-myoglobin-biotin conjugate, and paramagnetic particles coated with goat anti-biotin	A two site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with mouse monoclonal anti-myoglobin-alkaline phosphatase conjugate, mouse monoclonal anti-myoglobin-biotin conjugate, and paramagnetic particles coated with goat anti-biotin
Solid Support	Paramagnetic particles.	Paramagnetic particles.
Detection System	Chemiluminescent substrate.	Chemiluminescent substrate.
Calibrator	Liquid calibrators (frozen) prepared from buffered bovine serum albumin matrix with human cardiac Myoglobin at specified levels	Liquid calibrators (frozen) prepared from buffered bovine serum albumin matrix with human cardiac Myoglobin at specified levels
Analytical Range	1- 4000ng/mL	1- 4000ng/mL
Imprecision	This assay exhibits total imprecision of less than 8% across the expected physiological range.	This assay exhibits total imprecision of ≤ 10% across the expected physiological range.

Summary of Precision Study

Imprecision: Within-run assay imprecision was tested for concentrations from approximately 79 to 2405 ng/mL. The within-run imprecision ranged from 3.05 % CV to 4.32% CV. Between-run assay imprecision ranged from 6.49% CV to 8.58% CV. Total imprecision ranged from 7.32% CV to 9.25% CV.

Conclusion

Imprecision was the only performance characteristic revised in the Access Myoglobin assay and was not found to impact the safety and efficacy of the device. The modified Access® Myoglobin assay is substantially equivalent to the previously cleared Access® Myoglobin assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Beckman Coulter, Inc.
c/o Ms. Rachelle Parsons
Senior Regulatory Affairs Specialist, RAC
1000 Lake Hazeltine Drive
Chaska, MN 55318

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Re: k080481
Trade/Device Name: Access® Myoglobin and Access Myoglobin Calibrators on the Access Immunoassay Systems
Regulation Number: 21 CFR §866.5680
Regulation Name: Myoglobin Immunological Test System.
Regulatory Class: Class II
Product Code: DDR, JIT
Dated: February 16, 2009
Received: February 17, 2009

Dear Ms. Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): k080481

Device Name:

Access Myoglobin and Access Myoglobin Calibrators on the Access® Immunoassay Systems

Indication For Use:

Access Myoglobin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of myoglobin levels in human serum and plasma using the Access Immunoassay Systems.

Measurement of myoglobin aids in the rapid diagnosis of heart and renal diseases.

Prescription Use ____X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K080481